K120729

MAY 17 2012

510(k) Summary of Safety and Effectiveness

Company Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact Donovan May
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-7981
Fax: (513) 337-2793
Email: dmay3@its.jnj.com

Date Prepared March 8, 2012

Device Name Trade Name: HARMONIC ACE® Shears + Adaptive Tissue Technology
Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Predicate Device

Harmonic ACE® Curved Shears with Pistol Handle and Hand Control cleared under K060245 on April 7, 2006

Device Description:

The Ethicon Endo-Surgery HARMONIC ACE® Shears + Adaptive Tissue Technology are used for coagulation and mechanical transection of soft tissue during laparoscopic and open procedures. The devices allow the surgeon to grasp, coagulate, and transect soft tissue with a single instrument. The devices are hand-actuated with a shaft and tissue effector that can be rotated. The energy delivery can be activated with hand activation or with an optional generator foot switch.

Indications for Use:

The HARMONIC ACE® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.

Technological Characteristics: The Ethicon Endo-Surgery HARMONIC ACE® Shears + Adaptive Tissue Technology incorporate most of the same technological characteristics as that of the predicate devices with an ergonomic handle and redesigned blade geometry. Additionally, a change was made to several patient contacting materials with respect to the subject devices including the addition of a coating to the ultrasonic blade and a new pad material. The control mechanism was changed from a resistor identification to an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC ACE® Shears + Adaptive Tissue Technology.

Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone when there is little or no tissue between the instrument blade and tissue pads. To do this the generator monitors the thermal condition of the blade during device activation.

Performance Data: Bench testing and laboratory evaluations in an animal model including acute and 30-day chronic survival studies were conducted to demonstrate that the HARMONIC ACE® Shears + Adaptive Tissue Technology perform as intended.

Conclusion: The results of the bench top and animal model testing demonstrate that the HARMONIC ACE® Shears + Adaptive Tissue Technology are as safe and effective and perform as well as the identified legally marketed predicate devices for cutting and coagulating soft tissue and sealing vessels up to 5 mm in diameter, as measured in situ.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 17 2012

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Mr. Donovan May
4545 Creek Road
Cincinnati, Ohio 45242

Re: K120729
Trade/Device Name: HARMONIC ACE® Shears + Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 04, 2012
Received: May 07, 2012

Dear Mr. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use

510(k) Number (if known): K120729

Device Name: HARMONIC ACE® Shears + Adaptive Tissue Technology

Indications for Use:

The HARMONIC ACE® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120729